REMARKS

Claims 3-6, 8, 14, 21, 22, and 27-50 are pending. By this Amendment, claims 3, 5, 8, 14, and 22 are amended, claims 1, 7, 9-13, 15-18 and 23-26 are cancelled (claims 2, 19, and 20 having been cancelled previously), and claims 34-50 are added. Claims 3, 4, 21, 31-35, and 43-45 are withdrawn as being drawn to non-elected subject matter. No new matter has been incorporated into the application as a result of the amendments made herein.

An additional restriction requirement was made in the last Office Action and a constructive election made by the Examiner, thus withdrawing claim 21 from examination. The Office Action states that claim 21 is directed to an invention that is independent or distinct from the invention originally claimed because it is drawn to a method of use and the other pending claims are drawn to an apparatus. The Office Actions states that the amendment to claim 21 distinguishes this method from the originally presented method and that there would be a "serious burden on the examiner if restriction is not required as the inventions [the method and apparatus] have acquired a separate status in the art due to their recognized divergent subject matter" (clarification added). This reasoning is not understood as the method claim has already been examined including searching and substantive analysis as to its merits in two prior Office Actions. Their separate status did not previously pose a serious burden on examination so it is unclear how a clarifying amendment now poses a serious burden on examination. It is requested that claim 21 be rejoined for examination. It is further requested that all of the withdrawn claims be rejoined and examined upon the indication of allowable subject matter.

In the Office Action, claims 1, 5, 6, 10, 14, 16, 22 and 27-30 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,394951 to Taylor et al. (Taylor). Claims 1, 10, and 16 are canceled. Therefore, the rejection is addressed with respect to independent claims 14 and 22 and the relevant dependent claims.

The Office Action states that Taylor teaches a tissue approximation device having two elongate arms 3, an attachment means 144, adhesive pads 4 movably connected by elements 18 and 19 on at least a portion of the elongate arms, and a locking means 181 as claimed. Reference is made to the embodiments represented in Figs. 31a and 31b.

Taylor's surgical instrument is designed for stabilizing a beating heart during coronary artery bypass graft surgery. The embodiment shown in Figs. 31a and 31b includes interconnected shaft means 3 that permit contact members 1 to be moved with respect to each other. However, the contact members 1 are only positioned in parallel fashion relative to one another at a certain orientation since there is only one pivot point. When the scissors are moved the contact members 1 will swing in an arc and therefore not be truly parallel to each other. A friction means is affixed to the bottom surface 4 of each contact member 1. Application of a stabilizing force causes the tissue on either side of the target artery to be spread or compressed while the heart is stabilized. The elements 18 and 19, referred to in the rejection, are actually present in a different embodiment and allow a snap in member 16 to be removably attached to the bottom surface 4 of the contact member 1 by post 18 and port 19. They do not provide a movable connection.

In distinction, claim 14 is directed to a tissue approximation device comprising two elongate arms, an attachment means to secure the elongate arms to each other at one or more locations, adhesive pads **movably connected** on the ends of the elongate arms to anchor the tissue approximation device to the skin, and a locking means to lock the elongate arms in place relative to each other. The adhesive pads are spaced apart from the one or more locations of the attachment means in the direction of the elongate arms. The tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other. The adhesive pad has a first adhering surface having a center line and a connector formed of one of a male protruding mechanism and a female receiving mechanism. The connector is formed on an edge of the adhesive pad **offset** from the center line and slidingly engages the other of a male protruding mechanism and a female receiving mechanism disposed on the distal end of each of the elongate arms. Each adhesive pad is **rotatable** about the distal end of the elongate arm to which it is connected.

First, the embodiment shown in Figs. 31a and 31b of Taylor does not have a movable adhesive pad, especially one that is rotatable or is connected at the edge of an adhesive pad offset from the center line. Second, the connector elements 18, 19 noted in the Office Action, which are part of a different embodiment than that used in the rejection, do not provide for a movable connection and particularly not a rotatable connection. Third, none of the various embodiments of Taylor discloses an adhesive pad that is connected at its edge offset from the center line in a sliding manner to the end of an elongate arm. As explained in this application, the rotatable connection is designed to allow the adhesive pads to pivot about the end of the arm thus allowing the adhesive pads to conform to various anatomical structures, such as a wrist or a back (page 6, lines 26-29.) Further, the offset position of the connection provides a large clearance between the tongs and provides for better control of tissue eversion during approximation (page 9, lines 28-30.) Moreover, the rotatable pads of this invention allow the pads to be positioned in a parallel fashion unlike Taylor, in which the ends of the arms swing in an arc. As none of these features is disclosed or even suggested by Taylor, claim 14 cannot be anticipated by Taylor. Claim 14 is allowable, as are dependent claims 36, 37, 49, 50 and withdrawn claims 34 and 35.

Claim 22 also recites that the connector is a pivotal connector that connects one edge of the adhesive pad to the tong to pivot about the longitudinal axis of the respective arm, wherein the pivotal connector is one of a rod and a sleeve and the adhesive pad includes the other of the rod and sleeve. As noted above, Taylor does not disclose this combination of features. Claim 22 and dependent claims 27-30, including withdrawn claims 31-33, are allowable for at least these reasons.

Finally, it is noted that there is a reference in this section of the Office Action to Benetti with respect to claim 5, but it is Applicant's understanding that the rejection based on Benetti has been withdrawn. Thus, this reference is assumed to be a mistake and is not addressed herein.

Claims 12, 18, 23, and 24 are rejected under 35 U.S.C. §103(a) as being unpatentable over Taylor in view of U.S. Patent No. 4,821,719 to Fogarty. All of these

claims are canceled. However, the feature of the pivotal connector and rod and sleeve connector is present in claims 14, 22, 49 and 50 so the merits of the rejection are addressed below.

The Office Action adds Fogarty to teach of a device having an adhesive pad with a first surface 30a and a second surface 55 with male and female connecting mechanisms and asserts that it would have been obvious to provide releasable adhesive pads in Taylor in view of Fogarty.

Fogarty's device is directed to a vessel occluding instrument that has resilient pads 30 secured to the clamp ends of a pair of jaws. The embodiment identified in the Office Action, seen in Figs. 5 and 6, has a pad 30a with Velcro like loops on an elastomeric tube 54 having a passage 55 to slide over the distal end 52 of the clamp. First, there is no adhesive pad. Second, Fogarty's device clamps around a vessel and does not have an open position and a closed position in which adhesive pads, or any pads for that matter, are parallel and non-contiguous to each other. Further, Fogarty does not disclose of a rotatable connection. Tubes 54 are described as being **snugly** received around the jaw elements, which does not suggest rotatability. So, Fogarty does not remedy the deficiencies of Taylor. These deficiencies were pointed out in the last response, but have merely been repeated in this Office Action with no further explanation. Neither reference discloses or even suggests of the connection as claimed. For at least these reasons, Taylor as modified by Fogarty does not render the claims obvious. Claims 14, 22, 49, and 50 are allowable.

Claims 8 is rejected under 35 U.S.C. §103(a) as being unpatentable over Taylor in view of U.S. Patent No. 3,754,331 to Agnone. The Office Action cites Agnone as teaching of connecting pads to forceps with a ball and socket connection.

Claim 8 is now written in independent form and is directed to a tissue approximation device comprising two elongate arms, an attachment means to secure the elongate arms to each other at one or more locations, adhesive pads movably connected on the ends of the elongate arms to anchor the tissue approximation device to the skin,

and a locking means to lock the elongate arms in place relative to each other. The adhesive pads are spaced apart from the one or more locations of the attachment means in the direction of the elongate arms. The tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other . The adhesive pad has a first adhering surface and a second surface rotatably coupled to the distal end of each of the elongate arms by a ball and socket connector, wherein the second surface has one of a socket and a ball that communicates with the other one of a ball and a socket on the distal end of each of the elongate arms. The adhesive pad is rotatable around the ball about at least two axes.

Taylor does not disclose a ball and socket connector that is rotatable about at least two axes. The Office Action identifies elements 18 and 19 as a ball and socket (in the remarks directed to claim 10, for example). However, as described in col. 14, lines 20-28, element 18 is a post and element 19 is a port that connect snap-in member 16 to the contact member 1. The post 18 and port 19 are disposed in a pair and do not provide for any rotatability. Further, Taylor's scissors configuration causes the contact members 1 to swing in an arc and not be positioned in a parallel fashion as distinguished from the present invention due to the pivotal connector. As such, Taylor does not disclose or even suggest of the features of claim 8.

Agnone's forceps are designed for dental extraction. Beaks 22 and 24 are mounted on handle elements 12 and 14, respectively, and can be adjusted to engage a tooth by manipulating screws 30 and 32 that end in a ball and socket joint 36. The joint does not provide a rotatable connection, but rather is manually adjustable by manipulating the screws. Further, there are no adhesive pads and no elements that are mounted parallel and non-contiguous to each other. There is no cogent reason for suggesting that one of ordinary skill in the art of Taylor's device would look to a dental extraction device that has a hand manipulated beak for any modification. A curved clamping beak of a dental instrument would not be used to apply a stabilizing force to a beating heart. Further, there would be no way to manipulate the beak within a surgical chest cavity. Finally, even if such a combination could be made, the features of the claims would not be met as Agnone does not remedy the deficiencies of Taylor, since the

connectors as claimed are not taught. Claim 8 is not rendered obvious by the asserted combination. Claim 8 is allowable. Dependent claims 5, 6, 46-48 and withdrawn claims 3 and 4 are also allowable.

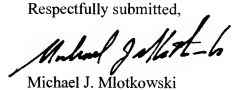
Claim 38 also recites a rotatable connector that connects the adhesive pad to the tong to pivot at least about the longitudinal axis and an axis substantially perpendicular to the longitudinal axis. The rotatable connector is a ball and socket that are snap fit together in an interference fit. None of the embodiments of Taylor, nor Taylor modified by Agnone, if possible, show this combination of features. Claim 38 and its dependent claims 39-42 and withdrawn claims 43-45 are allowable.

Claims 25 and 26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Taylor in view of Taylor. While these claims have been canceled, the snap fit feature is now present in claims 38 and 48 so the merits of the rejection are addressed below.

The Office Action recognizes that Taylor fails to explicitly teach of a connector that is a rotatable snap fit connector. It is asserted that it would have been obvious to modify Taylor's apparatus with a snap fit ball and socket to permit the contact members to self-align and engagingly conform to the surface of the tissue. The Office Action does not identify the ball and socket in Taylor, and Applicant finds no specific discussion for this feature. Further, it is unclear as to how a snap fit connection, which relates to the method of assembly, would permit the contact members to self-align and engagingly conform to the surface of the tissue. As no reasonable explanation of how the proposed modification would occur and no suitable reason for making the proposed modification has been provided, a prima facie case of obviousness has not been presented. Claims 38 and 48 are allowable.

It is submitted that the application is in condition for allowance. Should further issues requires resolution prior to allowance, the Examiner is requested to telephone the undersigned.

Respectfully submitted,



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